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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,769	04/04/2001	Milan S. Blake	NV1932	3657

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Baxter Healthcare Corporation
P.O. Box 15210
Irvine, CA 92614

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/17/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,769

Applicant(s)

BLAKE ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed September 29, 2003. Claims 1-10 have been cancelled. Claims 11-17 have been added.
2. Upon further consideration by the Examiner, the rejection of claim 4 under U.S.C. 103 is withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections Withdrawn

4. In view of Applicant's amendment the following rejections are withdrawn:
 - a) Objection to the specification, page 3, paragraph 2 of the previous Office action.
 - b) Objection to the specification, page 4, paragraph 3 of the previous Office action.
 - c) Objection to claim 2, page 4, paragraph 4 of the previous Office action.
 - d) Objection to claims 2 and 3, page 4, paragraph 5 of the previous Office action.
 - e) Objection to claims 2 and 3, page 4, paragraph 6 of the previous Office action.
 - f) Rejection of claim 3 under 35 U.S.C. 112, second paragraph, page 7, paragraph 9.
 - g) Rejection of claim 3 under 35 U.S.C. 112, second paragraph, page 7, paragraph 10.
 - f) Rejection of claim 10 under 35 U.S.C. 112, second paragraph, page 7, paragraph 11.

Objections and Rejections Maintained

5. The objection to the drawings is maintained for the reasons set forth on page 4, paragraph 7 of the previous Office Action.

The objection was on the grounds that the drawings are objected to by the Draftsman under 37 CFR 1.84 or 1.152. See the attached form PTO 948.

The new formal drawings submitted September 30, 2003 have been objected to by the Draftsman. Please see the new attached form PTO 948 for details. Correction is required.

6. The rejection under 35 U.S.C. 112, first paragraph is maintained for newly submitted claims 11-17 for the reasons set forth on pages 5-7, paragraph 8 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The claims are drawn to a method for producing PT comprising a *B. pertussis* cysteine desulfinate knockout mutant in a *B. pertussis* culture medium and isolating the PT from the culture medium and a method of enhanced production of PT comprising cultivating *B. pertussis* cysteine desulfinate knockout mutant.

The claims broadly encompass a genus of cysteine desulfinate genes. There is substantial variability among the species of cysteine desulfinate genes encompassed within the scope of the claims. The specification does not place any structure limitations on the cysteine desulfinate gene. The scope of the claims include numerous structural variants and the genus is highly variant because a significant number of structural difference between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the gene class are missing from the disclosure and the claims. No common structural attributes identify

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the members of the genus. Since there is no structure in the claim to define the cysteine desulfurase gene, the claimed genus includes cysteine desulfurase genes produced by other microorganisms. For Example, Mihara et al, (*The Journal of Biological Chemistry*, Vol. 272, No. 36, p. 22417-22424) teach that *Escherichia coli* appears to contain three nifS-like genes which encode NIFS-like protein (page 22417). Mihara et al teach that the NIFS-like proteins encoded by the nifS gene of *E. coli* has cysteine desulfurase activities. Mihara et al teach that nifS and NIFS-like proteins are found in a number of microorganisms (see Table III). Since the claimed genus encompasses genes of other microorganisms and genes yet to be discovered, the mere recitation of a "cysteine desulfurase knockout mutant" does not provide an adequate written description of the claimed genus since no structure accompanies the function of cysteine desulfurase activity. One skilled in the art would not recognize from the claimed disclosure that the applicant was in possession of the genus of nucleic acid sequences that are required to use the claimed method of producing PT comprising a *B. pertussis* cysteine desulfurase knockout mutant in a *B. pertussis* culture medium and isolating the PT from the culture medium. The recitation of "cysteine desulfurase knockout mutant" does not convey a common structure. As such, generic nucleic acid sequences that are unrelated via structure are highly variant and not conveyed by way of the written description in the specification at the time of filing. Therefore, the specification lacks written description for the highly variant genus of nucleic acid sequences that have cysteine desulfurase activity and one of skill in the would not recognize that Applicants had possession of the genus of the claimed genes for use in the method as instantly claimed method.

Applicant urges that the newly submitted claims are not susceptible to the section 112 rejections.

Applicant's arguments filed September 29, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show that the specification is enabled for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. The specification broadly describes a genus of cysteine desulfurase genes. There is substantial variability among the species of cysteine desulfurase genes encompassed within the scope of the claims. The specification does

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not place any structure limitations on the cysteine desulfinate gene. The scope of the claims include numerous structural variants and the genus is highly variant because a significant number of structural difference between genus members is permitted. While the use of probes, hybridization tools and mutagenesis techniques are known in the art, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the nucleic acid's sequence where nucleic acids modifications can be made with a reasonable expectation of success in obtaining the desired activity are limited in any nucleic acid molecule and the result of such modifications is unpredictable based on the instant disclosure.

The newly submitted claims encompass the use of DNA sequences intergrated into a *Bordetella pertussis* cysteine desulfinate gene. The specification does not place any structure limitations on the cysteine desulfinate gene nor does the specification place any structure limitations on the DNA sequences intergrated into a *Bordetella pertussis* cysteine desulfinate gene. Therefore, the specification lacks written description for the highly variant genus of nucleic acid sequences that have cysteine desulfinate activity and one of skill in the would not recognize that Applicants had possession of the genus of the claimed genes for use in the method as instantly claimed method.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the "recovery step". The claimed method comprises cultivating *Bordetella* bacteria and isolating the toxins produced, but fails to include a step for the recover of the toxin produced by the method.

8. Claim 17 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "set forth in Figure 7". Applicant is reminded, in accordance with *Ex parte Fressola* (27 USPQ 2d 1608, BPAI 1993), that modern practice requires that the claims to stand alone to define the invention. References in the claims to other parts of the specification are only permitted in very limited circumstances, which do not pertain to the instant situation. The instant claims are considered to be indefinite. Correction is required.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.


Vanessa L. Ford
Biotechnology Patent Examiner
December 9, 2003


NITA MINNIFIELD
PRIMARY EXAMINER
12/11/03